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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,154	08/27/2001	John R. Bianchi	RTI-112RIA	5282
52727 7590 01/31/2008 REGENERATION TECHNOLOGIES, INC. c/o MCANDREWS, HELD & MALLOY 500 WEST MADISON STREET 34TH FLOOR CHICAGO, IL 60661			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 01/31/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/941,154

Applicant(s)

BIANCHI ET AL.

Examiner

Paul B. Prebilit

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,30-32,35,39,61,64,68,69,71,72,74-78,80 and 102-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,30-32,35,39,61,64,68,69,71,72,74-78,80 and 102-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Drawings

The drawings were received on November 19, 2007. These drawings are approved for entry.

Claim Objections

Claims 102 and 105 are objected to because of the following informalities: claims 102 and 105 appear to be the same scope. Alternatively, if the Applicant considers the scopes of these claims distinct, it is unclear how broadly to interpret "ligamentous tissue.". Since the scopes of these claims are identical, the Applicant should cancel one of them in order to overcome this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 30-32, 107-109, and 111-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and

page 9 of the translation. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6). Coates, however, teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner's position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 12, 30-32, 107-109, and 111-112, Siebels meets the cleaning process limitations that are viewed as product-by-process limitations that do not clearly alter the structure of the product; see MPEP 2113 that is incorporated herein by reference. In particular, the cleaning process steps do not clearly suggest a product that would be cleaner than that disclosed by Siebels. Alternatively, one may view of the cleaning steps as having an effect on the final product structure. However, the Examiner asserts that any difference resulting from the process steps would at most result in only a slight difference between the claimed invention and the invention disclosed by Siebels. For this reason, the claimed invention is considered to be clearly obvious in view of Siebels and Coates.

Regarding claim 12, osteogenic material can be applied to the spaces of Coates including bone morphogenic protein (BMP) as claimed; see column 6, line 23 et seq.

Regarding claim 30, the spaces of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Therefore, all the pieces could be called a mineralized segment or a demineralized segment since each piece would contain at some of each material. Note that claim 31 allows a portion of the demineralized segment to mineralized.

Claims 35, 39, 61, 64, 68, 69, 71, 72, 74-78, 80, 102-106, 110, 113, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels and Coates as applied to claims 12, 30-32, 107-109, and 111-112 above, and further in view of Bonutti (US 5,545,222). Siebels meets the claim language as explained in the previous rejection but fails to teach fixing a soft piece of tissue between the first segment and the second segment as claimed. However, Bonutti teaches that it was known to fix soft or tendon tissue between bone tissue to form a composite graft; see column 14, lines 14-59. Bonutti also teaches that it was known to added antibiotic, hydroxyapatite, allograft or autografts to bone tissue to make larger pieces; see column 10, line 56 to column 11, line 4. Therefore, it is the Examiner's position that it would have been obvious to fix a soft piece of tissue between bone pieces in the Siebel invention as modified by Coates for the same reasons that Bonutti does the same.

Regarding claim 72, Coates teaches that it was known to use teeth or ridges for the vertebra-engaging surfaces; see Figures 12 to 20. Therefore, it is the Examiner's

position that it would have been obvious to do the same with Siebels as modified by Coates.

Response to Arguments

Applicant's arguments filed November 19, 2007 have been fully considered but they are not persuasive.

Particularly, the Applicant argues that neither Siebels nor Coates teaches a demineralized segment of allograft bone between mineralized segments. However, as explained in the previous Office action concerning claim 30, the spaces of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Therefore, all the pieces could be called a mineralized segment or a demineralized segment since each piece would contain at some of each material. Note that claim 31 allows a portion of the demineralized segment to mineralized.

Additionally, the Applicant's arguments follow the line of reasoning that it would not have been obvious to combine Siebels with Coates because Siebels wants easy assembly and Coates says that implants made of bone have been difficult to make.

In response, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and

cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. For this reason, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels.

The Applicant also argues that Siebels only means making implants out of plastic even when it states "solid disks can be manufactured of any biologically compatible material." This argument is not considered persuasive because the plain language of Siebels does not suggest such a limited understanding and because the use of plastics is considered to be mere exemplification or preference for making the device. Moreover, Coates provides the motivation to make the implant pieces of Siebels out of bone.

The Applicant also argues that there is no reasonable expectation of success for the combination of Coates with Siebels. However, the Examiner respectfully disagrees based upon his understanding of MPEP 2143.02. The fact that both the implant materials of Siebels and Coates can be machined to a particular shape and implanted to replace bones in the spinal column gives one a reasonable expectation of success.

With regard to the traversal of the claim 30 rejection and its discussion during the interview of May 1, 2007, the Examiner concluded that the claim 30 is still rendered obvious by Siebels and Coates because Coates teaches that mineralized segments can be coated with demineralized material. Since the demineralized segments of the

claimed invention can be partly mineralized (see claim 31), it is the Examiner's position that the mineralized segments of Coates that are coated with demineralized material can be said to be demineralized segments as well.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774

8/20

Fig. 20A

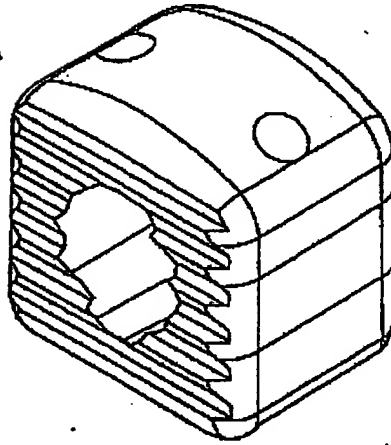


Fig. 20E

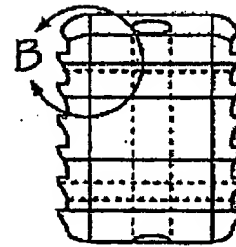


Fig. 20B

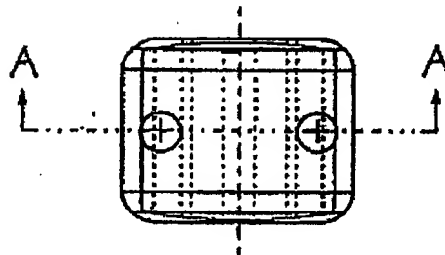


Fig. 20F

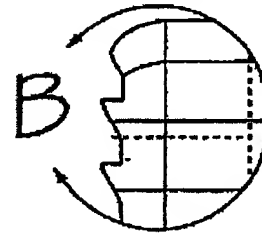


Fig. 20C

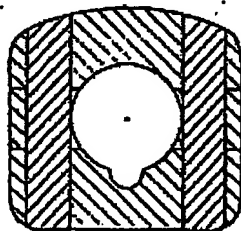


Fig. 20D

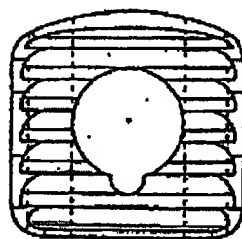
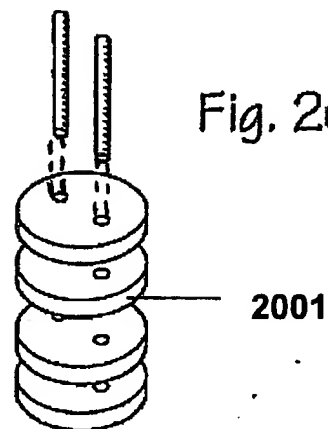


Fig. 20G



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for
Entry
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